



SAFETY DATA SHEET

Section 1: Identification			
Section 1, Identification			
Product			
Distributor	SOLA Pharmaceuticals		
	655 Highlandia Drive, Ste B		
	Baton Rouge, LA. 70810		
	Tel: 866.747.7365		
	Fax: 800.754.9550		
	<u>www.solameds.us</u>		
	info@solameds.us		
NDC Number	70512-797-01 / 24 (200mg per 100mL)		
	70512-798-01 / 24 (400mg per 200mL)		
	Section 2: Hazard(s) Identification		

Section 2, Hazard(s) Identification

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word Not Classified

Hazard Statements Not classified in accordance with international standards for

workplace safety.

Other Hazards An Occupational Exposure Value has been established for one or more of the

ingredients (see Section 8).

NoteThis document has been prepared in accordance with standards for

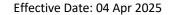
workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may

vary depending upon the potential for exposure in your workplace.

Section 3: Composition/Information on Ingredients

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Ingredient	CAS Number	EU EINECS/ELINCS List	CHS Classification	%
Hydrochloric Acid	7647-01-0	231-595-7	Skin Corr.1B (H314) STOT SE 3 (H335)	***
Sodium Hydroxide	1310-73-2	215-185-5	Skin Corr. 1A (H314)	***
Ropivacaine Hydrochloride	132112-35-7	Nost listed	Acute 4; H302 Aquatic Acute 3; H402 Aquatic Chronic 3; H412	0.2





Ingredient	CAS Number	EU EINECS/ELINCS List	CHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not listed	*
Sodium Chloride	7647-14-5	231-598-3	Not listed	*
Citric Acid, Anhydrous	77-92-9	201-069-1	Not listed	*
Sodium Citrate, Dihydrate	6132-04-3	Not listed	Not listed	*

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

* Proprietary
** to adjust pH

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mention in this Section, see Section 16

Section 4: First-Aid Measures

Section 4, First-Aid Measures

Description of First Aid Measures

Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation:

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:

For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure:

None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

None

Section 5: Fire-Fighting Measures

Section 5, Fire-Fighting Measures

Extinguishing Media:

Extinguish fires with CO2, extinguishing powder, foam, or water.

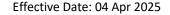
Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products:

Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards:

Fine particles (such as dust and mists) may fuel fires/explosions.





Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6: Accidental Release Measures

Section 6, Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:

Contain the source of the spill or leak. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7: Handling and Storage

Section 7, Handling and Storage

Precautions for Safe Handling

Minimize generating airborne mists and vapors. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:

Store as directed by product packaging.

Specific end use(s):

Pharmaceutical drug product

Section 8: Exposure Controls / Personal Protection

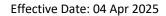
Section 8, Exposure Controls / Personal Protection

Control Parameters

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit 2ppm Australia PEAK 5 ppm 7.5 mg/m³ 5 ppm

Austria OEL - MAKs





	8 mg/m ³
Belgium OEL - TWA	5 ppm
Beigiani GEE 11171	8 mg/m ³
Bulgaria OEL – TWA	5 ppm
Bulguria OLL TWA	8 mg/m ³
Cyprus OEL – TWA	5 ppm
Cypius OLL – TWA	8 mg/m ³
Crock Donublic OFL TWA	8 mg/m ³
Czech Republic – OEL – TWA	
Estonia OEL – TWA	5 ppm
Common TDCS 000 TMA	8 mg/m ³
Germany – TRGS 900 – TWAs	2 ppm
0.51. 7114	3 mg/m ³
Greece OEL – TWA	5 ppm
051 7114	7 mg/m ³
Hungary OEL – TWA	8 mg/m ³
Ireland – OEL – TWAs	5 ppm
	8 mg/m ³
Italy OEL – TWA	5 ppm
	8 mg/m ³
Japan – OELs – Ceilings	2ppm
	3.0 mg/m^3
Latvia – OEL – TWA	5 ppm
	8 mg/m ³
Lithuania OEL – TWA	5 ppm
	8 mg/m ³
Luxembourg OEL – TWA	5 ppm
	8 mg/m ³
Malta OEL – TWA	5 ppm
	8 mg/m ³
Netherlands OEL – TWA	8 mg/m ³
Poland OEL – TWA	5 mg/m ³
Portugal OEL – TWA	5 ppm
	8 mg/m^3
Romania OEL – TWA	5 ppm
	8 mg/m^3
Slovakia OEL – TWA	5 ppm
	8 mg/m ³
Slovenia OEL – TWA	5 ppm
	8 mg/m ³
Spain OEL – TWA	5 ppm
	7.6 mg/m ³
Switzerland OEL – TWAs	2 ppm
	3.0 mg/m^3
Vietnam OEL – TWAs	5 mg/m ³
SODIUM CHLORIDE	
Latvia OEL – TWA	5 mg/m ³
Lithuania OEL – TWA	5 mg/m ³





SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit 2 mg/m^3 Australia PEAK 2 mg/m^3 Austria OEL – MAKs 2 mg/m^3 2 mg/m^3 Bulgaria OEL – TWA 1 mg/m³ Czech Republic OEL – TWA Estonia OEL – TWA 2 mg/m^3 France OEL – TWA 2 mg/m^3 Greece OEL – TWA 2 mg/m^3 2 mg/m^3 Hungary OEL – TWA Japan = OELs – Ceilings 2 mg/m^3 Latvia OEL - TWA 0.5 mg/m^3 2 mg/m^3 OSHA - Final PELS - TWAs Poland OEL – TWA 0.5 mg/m^3 2 mg/m^3 Slovakia OEL - TWA Slovenia OEL – TWA 2 mg/m^3 1 mg/m³ Sweden OEL – TWA 2 mg/m^3 Switzerland OEL – TWA

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Ropivacaine hydrochloride

Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

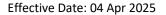
Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)





Respiratory protection:

Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

Section 9: Physical and Chemical Properties

Section 9, Physical and Chemical Properties

Physical State Solution

ColorNo data availableOdorNo data availableOdor ThresholdNo data available

Molecular Formula Mixture
Molecular Weight Mixture

Solvent Solubility No data available

Water Solubility Soluble

pH No data available

Melting/Freezing Point (°C) No data available

Boiling Point (°C) No data available

Partition Coefficient: (Method, pH, Endpoint, Value)

Ropivacaine hydrochloride

No data available Log P 2.15

SODIUM CHLORIDE No data available HYDROCHLORIC ACID

No data available

SODIUM HYDROXIDE

No data available

Water for Injection

No data available

Sodium citrate, dihydrate

No data available

Citric acid, anhydrous

No data available

Decomposition Temperature (°C)

No data available

Evaporation Rate (Gram/s)

No data available

Vapor Pressure (kPa)

No data available

Vapor Density (g/mL)

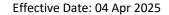
No data available

Relative Density

No data available

Viscosity

No data available





Flammability

Autoignition Temperature (Solid) (°C)

Flammability (Solids)

Flash Point (Liquid) (°C)

Upper Explosive Limits (Liquid) (% by Vol)

Lower Explosive Limits (Liquid) (% by Vol)

No data available

No data available

No data available

Section 10: Stability and Reactivity

Section 10, Stability and Reactivity

Reactivity No data available

Chemical Stability Stable at normal conditions

Possibility of Hazardous Reactions

Oxidizing Properties No data available

Conditions to Avoid Fine particles (such as dust and mists) may fuel fires/explosions
Incompatible Materials As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition

Products No data available

Section 11: Toxicological Information

Section 11, Toxicological Information

Information On Toxicological Effects

Short Term Anesthetic drug: may cause central nervous system and cardiovascular

system effects

Known Clinical Effects May cause tingling/itching (paresthesia), allergic reaction, decrease in blood

pressure (hypotension), decreased heart rate (bradycardia), respiratory

Depression

Acute Toxicity: (Species, Route, End Point, Dose)

Ropivacaine hydrochloride

 Rat
 IV
 LD50
 9.9 mg/kg

 Rat
 Oral
 LD50
 980 mg/kg

 Mouse
 Oral
 LD50
 300 mg/kg

SODIUM CHLORIDE

Sub-tenon injection (eye) $>42 g/m^3$ Rat LC50/1hr Rat Oral LD50 3 g/kg Mouset Oral LD50 4g/kg Rabbit Dermal LD50 >10 g/kg

HYDROCHLORIC ACID

Rat Oral LD50 238 – 277 mg/kg

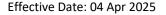
Citric Acid, Anhydrous

Rat Oral LD50 3000 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE

Skin Irritation Rabbit Mild Eye Irritation Rabbit Mild





Citric Acid, Anhydrous

Skin Irritation Rabbit Mild Eve Irritation Rabbit Severe

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effec(s))

Ropivacaine Hydrochloride

2 Generation Reproductive Toxicity Rat No route specified Dose not specified Negative

HYDROCHLORIC ACID

Bacterial Mutagenicity (Ames) Salmonella Negative In Vivo Micronucleus Rat Negative

Carcinogen Status

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

HYDROCHLORIC ACID

IARC Group 3 (Not Classifiable)

Section 12: Ecological Information

Section 12, Ecological Information

Environmental Overview

Releases to the environment should be avoided. Environmental properties have not been thoroughly investigated.

Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Ropivacaine hydrochloride

Green algaeEC5072 hours59 mg/LDaphnia magna (Water Flea)EC5048 hours34 mg/LBrachydanio rerio (Zebra Fish)LC5096 hours38 mg/L

Persistence and Degradatibility

No data available

Bio-accumlative Potential

Partition Coefficient: (Method, pH, Endpoint, Value)

Ropivacaine hydrochloride

No data available Log P 2.15

Mobility in Soil

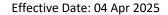
No data available

Section 13: Disposal Considerations

Section 13, Disposal Considerations

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.





Section 14: Transport Information

Section 14, Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: Regulatory Information

Section 15, Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Water for Injection

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory – United States TSCA – Sect 8(b)

Australia (AICS)

Not listed

Present

Present

REACH – Annex IV – Exemptions from the

Obligations of Register Present EU EINECS/ELINCS List 231-791-2

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting 1.0%
CERCLA/SARA Hazardous Substances and 5000 lb
Their reportable quantities 2270 kg

CERCLA/SARA – Section 302 Extremely

Hazardous TPQs 500 lb

CERCLA/SARA – Section 302 Extremely

Hazardous Substances EPCRA RQs
California Proposition 65
Inventory – United States TSCA – Sect 8(b)
Australia (AICS)
Standard for the Uniform Scheduling
For Drugs and Poisons
EU EINECS/ELINCS List
5000 lb
Not listed
Present
Schedule 5
Schedule 6
231-595-7

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory – United States TSCA – Sect 8(b)

Australia (AICS)

Present

Present

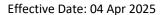
EU EINECS/ELINCS List

Not listed
Present
Present
231-598-3

Sodium Hydroxide

Sodium Chloride

CERCLA/SARA 313 Emission reporting Not listed **CERCLA/SARA Hazardous Substances and** 1000 lb Their reportable quantities 454 kg **California Proposition 65** Not listed Inventory – United States TSCA – Sect 8(b) Present Australia (AICS) Present Standard for the Uniform Scheduling Schedule 5 **For Drugs and Poisons** Schedule 6





EU EINECS/ELINCS List	215-185-5
Citric acid, anhydrous	
CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed
Inventory – United States TSCA – Sect 8(b)	Present
Australia (AICS)	Present
EU EINECS/ELINCS List	201-069-1
Sodium citrate, dihydrate	
CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed
Australia (AICS)	Present
EU EINECS/ELINCS List	Not listed
Ropivacaine hydrochloride	
CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed

EU EINECS/ELINCS List Not listed

Section 16, Other Information

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Section 16: Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

SOLA shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.